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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/541,191	10/11/95	KAYYEM	J A-62629/RFT

HM22/1114

ROBIN M SILVA  
FLEHR HOHBACH TEST ALBRITTON AND HERBERT  
SUITE 3400 FOUR EMBARCADERO CENTER  
SAN FRANCISCO CA 94111-4187

EXAMINER

JONES, D

ART UNIT	PAPER NUMBER
1619	29

DATE MAILED: 11/14/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

08/541,191

Applicant

Kajym et al

Examiner

D. Jones

Group Art Unit

1619

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☐ Responsive to communication(s) filed on 9/18/00
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1-22 is/are pending in the application.
- Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1-22 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
  - ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
  - ☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other \_\_\_\_\_

Office Action Summary

Art Unit: 1619

## APPLICANT'S INVENTION

1. Applicant's invention is directed to a delivery vehicle and methods of use thereof comprising (a) a first polymeric molecule, (b) at least one second polymeric molecule having a net charge opposite the first polymeric molecule and complexed with said first polymeric molecule and said second polymeric molecule is attached to at least one cell targeting moiety; and (c) at least one physiological agent attached to the first or second polymeric molecule or to a third polymeric molecule.

## RESPONSE TO APPLICANT'S ARGUMENTS

2. The Applicant's arguments filed 9/18/00 (Paper No. 28) to the rejection of claims 1-22 made by the Examiner under 35 U.S.C. 103 and double patenting have fully considered and deemed persuasive-in-part for the reasons set forth below.

### Statutory Double Patenting

3. The statutory type (35 U.S.C. 101) double patenting rejection is WITHDRAWN because Applicant has canceled claims 2-11 and 13-36 and amended claims 1 and 12 in the parent application (08/321,552).

### Obviousness-type Double Patenting

4. The obviousness-type double patenting rejection of claims 1-3, 10-13, 16-19, 21, and 22 over claims 1 and 12 of copending Serial No. 08/321,552 is **MAINTAINED** because in both cases the delivery vehicles comprise a first polymeric molecule (i.e., nucleic acid); a second

Art Unit: 1619

polymeric molecule (i.e., polylysine) attached to at least one target cell moiety; and a physiological agent (i.e., contrast agent, chelator complexed to gadolinium).

**103 Rejection**

5. The **rejection** of claims 1-22 under 35 U.S.C. 103(a) as being unpatentable over Wu et al (J. Biol. Chem., Vol. 266, No. 22, pp. 14338-14342, August 5, 1991) in view of Kornguth et al (US Patent No. 5,230,883) is **MAINTAINED** in the Office Action mailed 3/10/00, Paper No. 26, and those disclosed below.

In summary, Applicant reiterates the <sup>assertions</sup> asserts made previously in the response filed 8/10/99, Paper No. 22. However, as previously stated, Applicants arguments are not found persuasive for same reasons given in the Office Action mailed 3/10/00, Paper No. 26.

**COMMENTS/NOTES**

6. It is duly noted that in the response filed 8/10/99, Paper No. 22, Applicant asserts that the complexes of their invention show a surprising and unexpected benefit over the complexes of the prior art when the Kayyem et al (Current Bio., 2,:615-620 (1995)) document and in particular Figure 3 are reviewed.

In regards to Applicant's assertions of unexpected results, the Examiner's position is that Applicant has shown unexpected result when DNA/Tf/Gd-DTPA/PL is utilized (see Figures 2 and 3 of the instant invention). However, the data does not read on any possible four-component system, especially since the number of possible first polymeric molecule, second polymeric

Art Unit: 1619

molecule, cell targeting moiety, and contrast agent combinations as claimed is unlimited. Hence, if Applicant limits the invention to the embodiment for which unexpected results are shown, then, the claims would be allowable. In addition, Applicant <sup>address</sup> ~~must~~ to and overcome the obviousness-type double patenting rejection.

7. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to the Group 1600 fax machine at (703) 308-4556. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30; November 15, 1989.

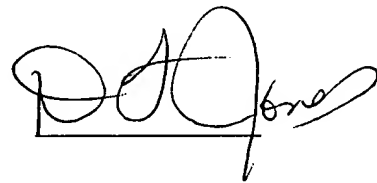
8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 1619

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (703) 308-4640. Examiner Jones can generally be reached from Monday through Friday between 7:00 a.m. and 3:30 p.m. If the Examiner cannot be reached, questions may be addressed to her supervisor, Diana Dudash, whose phone number is (703) 308-2328.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

A handwritten signature in black ink, appearing to read 'D. L. Jones', with a stylized flourish at the end.

D. L. Jones  
Primary Examiner  
Art Unit, 1619

November 9, 2000

**DAMERON L. JONES  
PRIMARY EXAMINER**